

Application No. 09/676,502
Art Unit 1651
September 15, 2003
Reply to Office Action of February 13, 2003

REMARKS/ARGUMENTS

In the "Reply After Final Under 37 C.F.R. § 1.116," filed June 13, 2003, certain claims were amended, and claims 53-59 were added. However, the June 13th Reply has not been entered (see the Advisory Action dated June 25, 2003). The June 13th Reply remains not entered, and Applicants submit this reply in response to the outstanding Office Action.

Applicants respectfully request entry of the present Reply since the number of issues is reduced. First, the Reply of June 13th has already been considered, wherein many of the same issues are addressed with the present Reply. Second, the number of issues is reduced since claims are being canceled herein.

Claims 1-12, 18, 19 and 39 have been previously canceled, and claims 14, 34, 42-44, and 48-51 are herein canceled. Claims 53-59 remained not entered. Claim 60 has been added. Claims 13, 23, 29, 33, 35, 36-38, 41 and 45 have been amended. Thus, claims 13, 15-17, 20-33, 35-38, 45-47, 52 and 60 are pending in the present application.

No new matter has been added by way of these amendments and new claim because each amendment and new claim is supported by the present specification and/or original set of claims. For example, the amendments to claims 13, 23, 33 and 41 and new claim 60 are supported by the present specification at page 13 and the various Examples. The amendments to claims 29 and 35-36 are editorial in nature. The

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amendments to claims 35, 37, 38 and 45 merely correct the dependencies of these claims since these claims depended on canceled claims. These amendments are for clarification and are not narrowing in any respect.

Based upon the above considerations, entry of the present amendment is respectfully requested. Further, the Advisory Action of June 25, 2003 indicates that the rejections with respect to the extracts of *Murraya* are overcome, and that "the additive extract renders claims unpatentable". Based on the amendments herein, Applicants respectfully request reconsideration and a finding of allowable subject matter.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Written Description Issues

Claims 13-52 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description of the invention. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner takes a position that the terms "extract" and "pharmaceutically acceptable additive" are not self-descriptive. Applicants submit that the artisan of ordinary skill understands the

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meaning of these terms in general. Also, there is detailed description of extracts according to the invention provided at, e.g., pp. 2-3 of the specification, at pp. 6-7 of the specification and in three working examples at pp. 8-9. Pharmaceutically acceptable additives are also well-known to the skilled artisan. Formulation of plant extracts is an old art. Furthermore, some specific pharmaceutically acceptable additives, which may or may not be active ingredients, are described at p. 4, lines 1-5.

The real issue seems to be set forth at the bottom of page 2 of the Office Action. The Examiner asserts that the "metes and bounds" of the terms "extract" and "pharmaceutically acceptable additive" are not clear from these terms. Applicants agree that these terms are generic, and therefore very broad. However, breadth of a claim term is not a matter of lack of written description. As explained above, these terms themselves are known in the art and are exemplified in detail in the specification.

Furthermore, not all of the claims are so broad as the Examiner asserts. Applicants note that the Examiner rejects claims 13-52 wholesale, without distinguishing the differing scope of the various claims. For instance, in claims 14-17 (now 15-16), specific "pharmaceutically acceptable additives" are named and amounts are provided. In claims 20 and 21, the chromatographic fingerprint of the active principles of the extract is described. Applicants submit

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that, for these claims at least, the instant rejection should not apply.

Still further, in the amended claims, the composition claim 13 is amended to recite process steps for obtaining the claimed extract. Additional claims 33, 55 and 56 also recite process steps for obtaining the extract. Thus, these claims, and claims dependent thereon, should not be subject to the instant rejection.

In fact, the Advisory Action of June 25, 2003 indicates that the rejections with respect to the extracts of *Muraya* are overcome. Thus, Applicants respectfully request reconsideration of the present claims in light of this finding, and withdrawal of this rejection.

Enablement Issues

Claims 13-52 also stand rejected under 35 U.S.C. § 112, first paragraph for alleged lack of enabling disclosure. The Examiner merely makes a broad, generalized assertion that the claims are not enabled by the description of the invention provided by the specification. Applicants respectfully submit that the Examiner has not provided any scientific explanation or sound reasoning as to why the disclosure is not enabling. Accordingly, the Examiner has not met his burden of establishing a *prima facie* lack of enablement and the instant rejection cannot stand ("The initial burden of establishing a *prima facie* basis to deny patentability to a claimed

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invention on any ground is always upon the examiner." See *Ex parte Parks*, 30 USPQ2d 1234, 1236 (citing *In re Oetiker*, 24 USPQ2d 1443 (Fed. Cir. 1992)).

Applicants further submit that, to the degree the Examiner is arguing that the breadth of the claims is undue, this is first but one factor among many to consider in weighing enablement. The Examiner furthermore has not considered that the scope of the various claims differs as explained above. Applicants would further point out that the specification provides three working examples of extraction and four case studies of human trials of the resulting extracts. Thus, Applicants submit that the instant rejection should certainly not be applied to such claims as recite process steps for obtaining an extract and as recite particular "pharmaceutically acceptable additives".

Also, based on the conclusions in the Advisory Action of June 25, Applicants respectfully request reconsideration and withdrawal of this rejection.

Indefiniteness Issues

Claim 14 is rejected under 35 U.S.C. § 112, second paragraph on the basis that the term "or extracts of plants selected" is not defined. Applicants have explained above that the skilled artisan would understand the term "extract". For instance, JP '180, cited by

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the Examiner as prior art utilizes this term in connection with ethanol extraction of plant parts. Similarly, Rameswak et al. (1999), also cited as prior art, describes acetone extracts of plant parts.

Further, this rejection is rendered moot since the disputed claims has been canceled. Thus, Applicants respectfully request that the instant rejection be withdrawn.

Issues under 35 U.S.C. § 102(b)

Claims 13, 14, 17 and 20-22, 33 and 51 stand rejected under 35 U.S.C. § 102(b) as anticipated by the abstract of JP 7138180 or by Ramsewak (1999). This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicants submit that JP '170 fails to describe salient features of the present invention. JP '170 describes ethanol extraction of "koenigii" but says nothing about treatment of asthma. The presently amended claim 13 recites that the composition comprises an amount of extract effective for treating asthma, which is not disclosed by JP '170. Also, the further additive extracts recited in claim 13 are not disclosed in JP '170.

The Examiner has also not accounted for further features of the invention as recited in, e.g., claims 16-17, which set forth particular amounts of extracts of particular plants. Such are not

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disclosed in the reference. Similarly, claims 20-21 describe a chromatographic fingerprint of the extract. There is no disclosure in JP '170 of such properties of any ethanol extract or in Ramsewak of such properties of an acetone extract. Nor, given the distinction in solvent selection in the present claim 13, is there any basis for the Examiner to assert inherency of these properties. In claims 22 and 33, the recitation of antioxidant activity of the extract is not disclosed by the JP '170 reference. As to Ramsewak, again the selection of a distinct solvent for extraction precludes an assertion of inherency by the Examiner. All of these features of the claims distinguish the present invention from the cited reference and have not been addressed by the Examiner. Accordingly, these rejections should be withdrawn.

Claims 40-45 stand rejected under 102(b) as anticipated by the Kartini et al. abstract. Claims 42-44 are canceled, rendering the rejection moot as to those claims. Also, this rejection is respectfully traversed as to the other pending claims. Reconsideration and withdrawal thereof are requested for the following reasons.

The Examiner cites Kartini as describing a methanol, chloroform or petroleum ether extract of *M. koenigii*. Kartini is distinguished from the invention of at least claims 44-45, in that the solvent utilized by Kartini is distinct from the solvents recited in the

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process steps of claims 44-45 (now recited in the present claim 41). Furthermore, Kartini fails to disclose the anti-asthmatic properties of an extract of *M. koenigii* as recited in claim 40. Accordingly, the instant rejection should be withdrawn.

Claims 46-47 and 49-50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kartini. The Examiner asserts that the process parameters of extraction temperature and reduced pressure evaporation of the solvent are obvious to the skilled artisan. Claims 47-50 are canceled, rendering the rejection of these claims moot. Further, Applicants respectfully submit that claim 46 is patentable on the basis of features recited in claim 41 as explained above.

Conclusion

Applicants submit that the present application well describes and claims patentable subject matter, and is patentably distinct over the cited references. Thus, reconsideration and withdrawal of all rejections is respectfully requested.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

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Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell (Reg. No. 36,623) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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